REMARKS

Reconsideration of the present application in view of the above amendments and the following remarks is respectfully requested. Claims 8, 9, 11, 12, 27-30 and 34-37 are under examination. By the above amendment, claims 8, 9, 11 and 12 have been canceled as well as non-elected claims 1-7, 10, and 13-26, and claims 27-30 and 34-37 have been amended to more specifically define certain aspects of the claimed subject matter. These amendments have been made without acquiescing to the grounds for rejections and are made without prejudice to any subject matter modified and/or removed by the above amendment in a related divisional, continuation and/or continuation-in-part application. No new matter has been added.

Applicants acknowledge that the previous rejection of claims 8, 9, 11, 12, 27-30 and 34-37 under 35 U.S.C. § 101 has been withdrawn.

Rejection Under 35 U.S.C. § 112, First Paragraph (enablement)

Claims 8, 9, 11, 12, 27-30 and 34-37 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. More particularly, the Examiner asserts that Applicants' disclosure has not sufficiently provided parameters which define or characterize the oligonucleotides germane to the invention, such as structure, size and sequence, necessary to practice the claimed invention. The Examiner also asserts that the specification has not provided sufficient guidance as to which regions of the target sequences are specific to diagnosing prostate cancer and to which the oligonucleotides must hybridize in order to detect prostate cancer. The Examiner also asserts that the specification does not suitably provide information as to how to design oligonucleotide fragments and how to screen for these oligonucleotides.

Applicants respectfully traverse this rejection.

Applicants respectfully submit that the specification provides more than adequate disclosure to allow an artisan of ordinary skill to make and use the currently claimed detection methods, without undue experimentation, using well established techniques described in the subject specification and readily available in the art to which this invention pertains. Applicants

have disclosed the specific structures of the polynucleotide sequences of SEQ ID NOs: 67, 107, 308 and 311, and have identified that these sequences exhibit a prostate cancer-associated expression profile sufficient to support their utility in diagnostic methods. This much has been acknowledged by the Examiner. Applicants further submit, however, that this disclosure also more than adequately leads the skilled artisan to understand that sequences related to those set forth in SEQ ID NOs: 67, 107, 308 or 311, *e.g.*, oligonucleotide and polynucleotide sequences capable of hybridizing to a sequence of SEQ ID NOs: 67, 107, 308 or 311, primers effective for amplifying a sequence of SEQ ID NOs: 67, 107, 308 and 311 in a RT-PCR reaction, *etc.*, are also useful for detecting over-expression of a sequence of SEQ ID NOs: 67, 107, 308 or 311 in a biological sample, based upon their sequence similarity to, and thus hybridization specificity for, the specific sequences of SEQ ID NOs: 67, 107, 308 or 311. Based upon firmly established principles of nucleic acid hybridization, a skilled artisan would have no difficulty understanding that sequences related to SEQ ID NOs: 67, 107, 308 and 311 can be used for detecting expression of a sequence of SEQ ID NOs: 67, 107, 308 and 311 in a biological sample, and thus for the detection of prostate cancer, despite the fact that the related sequences may not be identical with the precise sequences set forth in SEQ ID NOs: 67, 107, 308 and 311.

With respect to the Examiner's assertion that the specification has not provided sufficient guidance as to which regions of the target sequences are specific to diagnosing prostate cancer, Applicants respectfully submit that the skilled artisan, in view of the instant disclosure, would understand and appreciate that the sequences of SEQ ID NOs: 67, 107, 308 and 311 represent cDNA sequences that possess prostate cancer-associated expression profiles. Accordingly, the skilled artisan would also recognize that all regions of the target cDNA sequences are expressed in the same prostate cancer-associated fashion and may be employed or targeted for detection according to the claimed methods. Guidance as to which regions of the claimed sequences possess specificity for use in the claimed methods is not necessary when the skilled artisan would understand that the entirety of the claimed sequences are expressed in the same prostate cancer-associated fashion and may be used in the claimed methods. This understanding on the part of the skilled artisan is submitted to be soundly based upon fundamental principles of molecular biology.

With regard to the Examiner's assertion that the specification does not suitably provide information as to how to design oligonucleotide fragments and how to screen for these oligonucleotides, Applicants submit that the design of and use of polynucleotide primers and probes having hybridization specificity for a target polynucleotide sequence is well described by the subject specification (*e.g.*, page 6, line 21 to page 14, line 17) and, further, is well within the purview of an artisan of ordinary skill. One need not practice undue experimentation in the art of molecular biology in order to understand with a reasonable degree of predictability, and confirm using only routine techniques, whether a fragment of a target polynucleotide sequence, or a sequence sharing a high degree of structural identity with a target polynucleotide sequence, would be capable of specifically hybridizing to that target polynucleotide sequence under a defined set of hybridization conditions.

Accordingly, in view of the above, the use of sequences related to SEQ ID NOs: 67, 107, 308 and 311 in Applicants claimed methods, *e.g.*, sequences capable of hybridizing to SEQ ID NOs: 67, 107, 308 and 311, is submitted to fall squarely within the scope of subject matter enabled by the specification at the time this application was filed, and would be clearly recognized as such by the skilled artisan.

In the interest of advancing prosecution related to certain aspects of the claimed invention, Applicants have amended claims 27-30 and 34-37 such that the claims are drawn to PCR-based methods for detecting prostate cancer, and for monitoring the progression of prostate cancer, using at least two oligonucleotide primers in a polymerase chain reaction, wherein said oligonucleotide primers are specific for, and effective for amplifying in a polymerase chain reaction, an expressed polynucleotide sequence of any one of SEQ ID NOs: 67, 107, 308 and 311. Support for these amendments can be found in the specification as originally filed, for example at page 38, lines 6-11. Moreover, Applicants' specification offers detailed guidance with respect to methods for the detection of prostate cancer using PCR-based approaches (*e.g.*, page 38, line 6 to page 39, line 8, and elsewhere). These and other related PCR and expression detection techniques are indeed well known to the skilled individual and can be practiced in the context of the claimed invention without any undue experimentation and with a reasonable expectation of success.

Reconsideration of the Examiner's rejection is respectfully requested.

The Commissioner is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the claims remaining in the application are now believed to be in condition for allowance. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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